

**Notice of Allowability**

Application No.

10/581,591

Examiner

Erich A. Leeser

Applicant(s)

KAWAHARA ET AL.

Art Unit

1624

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10-12-07.
2. ☒ The allowed claim(s) is/are 1-25.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

/James O. Wilson/  
Supervisory Patent Examiner  
Art Unit 1624

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: August 27, 2007 and November 16, 2007 .

## ALLOWANCE

1. Claims 1-25 are allowed. Applicant has amended claims 19-25 and cancelled claim 26.

### *Examiner's Amendment*

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In a telephone discussion dated December 7, 2007, Applicant gave Examiner authorization for this Examiner's Amendment.

3. The Application has been amended as follows:

Claim 1: AMENDED: in line 14 on page 3, insert "C1-6 alkyl, C1-6 haloalkyl, C2-7 alkylene, and" before the word "phenyl."

Claim 2: AMENDED: in line 10 on page 6, insert "C1-6 alkyl, C1-6 haloalkyl, C2-7 alkylene, and" before the word "phenyl."

Claim 22: HAS BEEN AMENDED TO READ AS FOLLOWS: A therapeutic composition for an inflammatory disease, comprising the compound according to claim 1 or 2, the salt thereof or the hydrate of the foregoing in association with a pharmaceutically acceptable additive.

Claim 23: HAS BEEN AMENDED TO READ AS FOLLOWS: A method of treating an inflammatory bowel disease, irritable bowel syndrome, rheumatoid arthritis, psoriasis, multiple

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sclerosis, asthma or atopic dermatitis in a patient, comprising administering to said patient a therapeutic composition containing the compound according to claim 1 or 2, the salt thereof or the hydrate of the foregoing in association with a pharmaceutically acceptable additive.

Claim 24: HAS BEEN AMENDED TO READ AS FOLLOWS: A method of treating an inflammatory bowel disease in a patient, comprising administering to said patient a therapeutic composition containing the compound according to claim 1 or 2, the salt thereof or the hydrate of the foregoing in association with a pharmaceutically acceptable additive.

Claim 25: HAS BEEN AMENDED TO READ AS FOLLOWS: A method of treating ulcerative colitis or Crohn's disease in a patient, comprising administering to said patient a therapeutic composition containing the compound according to claim 1 or 2, the salt thereof or the hydrate of the foregoing in association with a pharmaceutically acceptable additive.

#### ***Information Disclosure Statement***

4. References disclosed in the IDS dated August 27, 2007 and November 16, 2007 are hereby made of record.

#### ***Reasons for Allowance***

5. The following is an Examiner's statement of reasons for allowance: the elected invention is free of the prior art and the form of the application is acceptable. The closest prior art is Morgans et al., WO 2005/005382, which teaches similar compounds. The difference between the compounds of the reference and the instant compounds is that instant R10 requires a "5- to

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10-membered cycloalkyl" whereas the variable substituents located at the corresponding position on the compounds of the reference are all acyclic.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

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Supervisory Patent Examiner  
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**Erich A. Leeser**

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